# Technical Bulletin: Accreditation of healthcare processes delivered between multiple entities

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This is an update to the previous Technical Bulletin: *Medical laboratory process delivered by multiple legal entities* published on 11th September 2019.

## Introduction

This document outlines the UKAS assessment approach where the applicant or accredited organisation does not directly manage all stages of the end to end process; in other words where critical parts of the pre-examination, examination/testing or post examination process are carried out by (an)other organisation/organisations. This includes organisations which are a different legal entity and/or a different accreditation reference.

This document will assist organisations in the formulation of effective policies and procedures when they are seeking accreditation for such examinations and provide assessors with support in the assessment process.

## Scope

This document applies to applicant and accredited healthcare organisations.

## Terminology

Examination/test - to determine the value or characteristics of a property.

Pre-examination processes/pre-analytical phase - processes that start, in chronological order, from the clinician's request and include the examination request, preparation and identification of the patient, collection of the primary sample(s), and transportation to and within the organisation, and end when the examination begins.

Post-examination processes/post-analytical phase - processes following the examination including review of results, retention and storage of clinical material, sample (and waste) disposal, and formatting, releasing, reporting and retention of examination results.

Testing - determination of one or more characteristics of an object of conformity assessment, according to a procedure.

**Policy**

The overall process with roles and responsibilities shall be clearly defined, and formal agreement/contracts(s) which are legally enforceable shall be in place between the legal entities involved.

The organisation taking responsibility for ensuring the whole process including pre/post examination/analytical stages meets the needs of the user(s) and the requirements of ISO/IEC 17025, ISO 15189 and/or other healthcare standard shall be clearly defined.

There shall be bi-directional governance arrangements between the entities, including arrangements for sample traceability, investigating and responding to complaints or nonconforming work as relevant to the examination.

Each stage will have a defined input (e.g. sample/patient attendance or referral) and output (report/result) as relevant to the process. Acceptance criteria shall be defined and implemented for input and output for the part of the process carried out by each entity.

Where a service accredited to either ISO 15189, ISO/IEC 17025 or other healthcare standard is not available for a stage of the examination process (including any pre/post stages) the organisation taking responsibility for ensuring all stages meet the users' needs and requirements of the relevant standard shall assure themselves of the competence of the individual organisations involved to undertake the work.

The responsible organisation shall demonstrate competence to carry out this review.

Contracts/formal arrangements between the parties shall include this requirement, unless the organisations to be used are otherwise specified.

The applicant/accredited organisations agreement(s) with users of their services shall include details associated with the phased examination approach.

Where relevant the input (sample type) and the expected output will be clearly defined on the schedule of accreditation.

UKAS will assess the appropriateness and effectiveness of the above arrangements.

**References**

ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.

ISO 15189 Medical laboratories - Particular requirements for quality and competence.

QSI Standard The Quality Standard for Imaging.

IQIPS Standard Improving Quality in Physiological Services.

BS 70000 Medical physics, clinical engineering and associated scientific services in healthcare. Requirements for quality, safety and competence.